IN THE

Supreme Court of the United States

OCTOBER TERM, 1944

No.

RALADAM COMPANY, as Claimant of 62 Packages, more or less, of Marmola Prescription Tablets,
Petitioner,

vs.

UNITED STATES OF AMERICA,
Respondent.

BRIEF IN SUPPORT OF THE FOREGOING PETITION FOR A WRIT OF CERTIORARI

OPINIONS OF THE COURTS BELOW

The opinion of the trial Court herein (R. 1298-1315) is reported in 48 F. Supp. 878; and the opinion of the Circuit Court of Appeals for the Seventh Circuit, affirming the same (R. 1353-9), is reported in 142 F. (2nd) 107. The pertinent parts of these opinions are discussed in the foregoing petition (*supra*, pp. 6-7, 10).

JURISDICTION

A statement of the grounds on which the jurisdiction of this Court to grant the foregoing petition is invoked and a statement of the reasons for granting the same are set forth therein (*supra*, pp. 12, 14-18). To avoid repetition, they are incorporated in this brief by reference.

STATEMENT OF THE CASE

A statement of the case is set forth in the foregoing petition (*supra*, pp. 1-11). Likewise, to avoid repetition, it is incorporated in this brief by reference.

SPECIFICATION OF ERRORS

The Circuit Court of Appeals for the Seventh Circuit erred, in affirming the decision of the trial Court herein, as follows:

I. In holding—contrary to the applicable decision of this Court in *McDermott v. Wisconsin*, 228 U. S. 115, 133—that the test of misbranding under Sec. 502(j) is whether there are any potential dangers *inherent* in *self-medication* with *effective* dosages of a drug, instead of holding that "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding this question; or, in other words, in failing to hold that Sec. 502(j) is purely a *labeling* provision the violation of which is to be determined accordingly.

II. In holding that Sec. 502(j) is subject to a construction which will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medica-

tion, because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription—*despite* the wording of the other *misbranding* provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history.

III. In failing to hold that the construction which it and the trial Court have placed on Sec. 502(j) casts grave doubt upon its constitutionality.

IV. In failing to hold that the record herein does not contain evidence which—as a matter of law—will support a finding that Marmola is misbranded under Sec. 502(j) when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly.

SUMMARY OF ARGUMENT

I. This Court held in *McDermott v. Wisconsin*, 228 U. S. 115, 130, 131, 132-3, that "the *label* is the *means* of *vindication* and the *basis* of *punishment*," in determining whether a drug is misbranded under a *labeling* provision —like Sec. 502(j); and that "this is the *only practical* or *sensible* construction" of such a provision. Consequently, the respective decisions of the lower Courts herein—holding, in effect, that a drug is misbranded under Sec. 502(j) regardless of the propriety of its labeling, if there are any potential dangers *inherent* in its use for self-medication—is in conflict with the decision of this Court in *McDermott v. Wisconsin, supra;* and this alone should furnish a sufficient reason for granting the foregoing petition for a writ of certiorari.

Furthermore, the conclusion reached by this Court in the *McDermott* case *is* "the *only practical* or *sensible* construction" of a *misbranding* provision—like Sec. 502(j). This is so for two outstanding reasons, among others, *viz.*, it is a cardinal principle of statutory construction, often enunciated and applied by this Court, that a statute

must be construed according to the *natural import* of its language, in order to carry out the legislative intent disclosed thereby, with the result that a *misbranding* provision—like Sec. 502(j)—must be construed as purely a *labeling* provision the violation of which is to be determined accordingly, because the *very term* "misbranded" connotes "*mislabeled.*" and, therefore, can define *only* a *labeling* offense; and it is an equally well-settled principle of statutory construction that a statute should be given a *sensible* construction which will avoid *absurd* results—such as making it impossible to label any useful drug known to *materia medica* for *self-medication* in *effective* dosages, without rendering it misbranded under Sec. 502(j), *per se*.

II. The wording of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history make it crystal clear that Congress did not intend Sec. 502(j) to be construed in such a manner as to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication, because of the potential dangers *inherent* therein. Instead, the misbranding provisions of the statute—like Sec. 502(j)—are designed *merely* to make self-medication safer and more effective by requiring *adequate* and *proper labeling* of all drugs put on the market for such purposes. Hence, the contrary construction placed on Sec. 502(j) by the lower Courts herein is manifestly unsound and must be rejected; and it is submitted that the need for a proper settlement of this important question of federal law by this Court, at the earliest possible moment, should impel the granting of the foregoing petition for a writ of certiorari.

III. An additional reason for granting the foregoing petition for a writ of certiorari is that the construction placed on Sec. 502(j) by the lower Courts herein casts grave doubt upon its constitutionality, as being (1) an improper interference by Congress in a matter of purely

local concern; (2) an unwarranted attempt to prohibit the right of individual citizens of this country to medicate themselves with effective dosages of useful drugs—like desiccated thyroid—without any showing of harm to the public, in general, as a result of their so doing; and (3) a provision the violation of which entails severe penalties and forfeitures without furnishing any fair or ascertainable standard for gauging compliance therewith in advance of prosecution and punishment.

IV. Finally, the foregoing petition for a writ of certiorari should be granted because the record in this case does not contain evidence which—as matter of law—will support a finding that Marmola is misbranded under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly. All that the Government has proved—or really sought to prove—in this case is that there are certain potential dangers *inherent* in self-medication with desiccated thyroid in the Marmola dosage; and such proof is immaterial on the question of whether Marmola is *misbranded, viz.*, mislabeled, under Sec. 502(j).

ARGUMENT

I

In view of the applicable decision of this Court in *McDermott v. Wisconsin*, 228 U.S. 115, Sec. 502(j) is purely a *labeling* provision the violation of which is to be determined accordingly, with the result that "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding whether a drug is misbranded thereunder; and, hence, a decision that a properly labeled drug is misbranded under Sec. 502(j) merely because of the potential dangers *inherent* in self-medication with *effective* dosages thereof is in conflict with this Court's decision in *McDermott v. Wisconsin, supra.*

As has been more fully pointed out in the foregoing petition for a writ of certiorari (*supra*, pp. 14-15), this Court held in *McDermott v. Wisconsin*, 228 U. S. 115, 130, 131, 132-3, that, under "the only practical and sensible construction" of a *misbranding* provision—like Sec. 502(j)—"the *label* is the *means* of *vindication* and the *basis* of *punishment*" in deciding whether a drug is misbranded thereunder. Hence, the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, is clearly in conflict with the applicable decision of this Court in *McDermott v. Wisconsin, supra*, because it holds, in effect, that a drug is misbranded under Sec. 502(j)—regardless of the propriety of its labeling—if there are any potential dangers *inherent* in *self-medication* with *effective* dosages thereof.

Furthermore, the conclusion reached by this Court regarding the proper construction of a *misbranding* provision—like Sec. 502(j)—is sound and in accordance with well-settled principles of statutory construction as will be more fully hereinafter pointed out.

A. A statute should be construed according to the natural import of its language, in order to carry out the legislative intent disclosed thereby.

The authorities are unanimous on the necessity of construing a statute according to the natural import of its language. In the case of *Lake County v. Rollins*, 130 U.S. 662, 670-1, this Court lucidly set forth the principle under discussion as follows:

> "To get at the thought or meaning expressed in a statute, a contract or a constitution, the first resort, in all cases, is to *the natural signification of the words*, in the order of grammatical arrangement in which the framers of the instrument have placed them. If the words convey a definite meaning which involves no absurdity, nor any contradiction of other parts of the instrument, then that meaning, apparent on the face of the instrument, must be accepted, and neither the courts nor the legislature have the right to add to it or take from it." (Italics ours)

More recent cases affirming and applying the foregoing principle are:

> *Thompson v. United States*, 246 U. S. 547,551; and
> *Magnano v. Hamilton*, 292 U. S. 40, 46-7.

The *Magnano* case is particularly apt because it was held that the statute under consideration therein was "plainly a taxing act" because of the language in which it was phrased.

1. Sec. 502(j) is a *misbranding* provision which speaks *solely* in terms of "labeling" and makes purely "labeling" requirements, with the result that it is to be construed and its violation determined accordingly.

Applying the elementary principle of statutory construction set forth in *Lake County v. Rollins*, 130 U. S. 662, 670-1, and the other cases immediately hereinabove discussed, it is clear that Sec. 502(j) is purely a *labeling* provision the violation of which is to be determined accordingly. This is so because Sec. 502(j) reads as follows:

> "A drug or device shall be deemed to be *misbranded*—
>
> "If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the *labeling* thereof." (Italics ours)

To *paraphrase* the ruling of this Court in *Magnano v. Hamilton*, 292 U. S. 40, 46-7:

> "Sec. 502(j) is in form plainly a *labeling* provision, with nothing in its terms to suggest that it was intended to be anything else."

2. The true test of compliance, or non-compliance, with a *misbranding* provision is—of necessity—the *propriety* of the *labeling* of a drug, *and that alone;* with the result that a drug is not "dangerous to health" within the meaning of Sec. 502(j) *unless* it is *made so* by improper labeling.

When it is appreciated that Sec. 502(j) speaks *solely* in terms of "labeling" and is, therefore, purely a *labeling* provision, the proposition that the *propriety* of the label-

ing of a drug furnishes the sole criterion of whether it is misbranded thereunder, would appear to follow—*a fortiori*. Accordingly, in *United States v.* 36 *Bottles of Gin* (C.C.A., 3rd), 210 Fed. 271, 272, the Circuit Court of Appeals for the Third Circuit ruled that the question of whether an article was *misbranded* under the Pure Food and Drug Act of 1906 depended *solely* on its *labeling*, as follows:

> "* * * This the label, *and the label alone*, must determine. * * *" (Italics ours)

As a matter of fact, if one stops to consider the ordinary and accepted meaning of the term "misbranded," it is apparent that Sec. 502(j) is directed solely against *mislabeling*, with the result that its violation is to be determined accordingly. This is so for the obvious reason that the very term "misbranded" means "mislabeled," and, therefore, can define *only* a *labeling* offense.

3. Consequently, any so-called "potential" dangers which may be "inherent" in self-medication with a *properly labeled* drug *after* it has been shipped in interstate commerce, are *immaterial* on the issue of whether it is *misbranded* for shipment under a *labeling* provision—like Sec. 502(j).

To recapitulate: this Court said, in *McDermott v. Wisconsin*, 128 U. S. 115, 133: "The *label* is the *means* of *vindication* or *the basis of punishment* in determining the character of the *interstate shipment* dealt with by Congress"; and, as the Circuit Court of Appeals for the Third Circuit put it in *United States v.* 36 *Bottles of Gin* (C.C.A., 3rd), 210 Fed. 271, 272, the issue of misbranding is one which "the label, *and the label alone*, must determine."

This being so, it is clear that any *dangers* which may be "inherent" in the *use*, or misuse, of a *properly labeled* drug for self-medication, following its interstate ship-

ment—which dangers concededly cannot be eliminated by any form of labeling—are wholly immaterial on the issue of whether it was misbranded *at the time* of shipment, *viz., mislabeled,* for shipment in interstate commerce.

In other words, it is difficult—if not impossible—to perceive how a drug that is *properly labeled* and, therefore, validly *branded* under the statute for shipment in interstate commerce, can thereafter suddenly become misbranded, without any change in its labeling, merely because of the possibility that some untoward consequences may arise from its use in violation of the directions, instructions, and limitations upon its use set forth in the labeling thereof. An explanation of how this transformation can take place without any visible change in the labeling—if forthcoming and comprehendable—will be most enlightening, to say the least.

B. Sec. 502(j) should be given a sensible construction which will avoid absurd results.

It is an equally well settled principle of statutory construction that a statute should be construed in a *sensible* manner, in the light of its language and purpose, so that *absurd results* may be avoided. The principle under discussion is well stated by this Court in the recent case of *Haggar Co. v. Helvering,* 308 U. S. 389, 394, as follows:

> "All statutes must be construed in the light of their purpose. A literal reading of them *which would lead to absurd results is to be avoided* when they can be given a reasonable application consistent with their words and with the legislative purpose. * * *" (Italics ours)

Earlier decisions of this Court to the same effect are the following;

> *United States v. Katz,* 271 U. S. 354, 357; and *Armstrong Co. v. Nu-Enamel Corp.,* 305 U. S. 315, 332-3.

1. If Sec. 502(j) is construed to require the recommendation of a dosage which can be taken *with impunity* in violation of the instructions for and limitations upon its use set forth in the labeling thereof it cannot be complied with because there is no effective dosage of any efficacious drug known to *materia medica*, which can be taken with safety under such conditions.

The trial Court held expressly (R. 1313)—and the Circuit Court of Appeals for the Seventh Circuit, in affirming the trial Court's decision, held, in effect (R. 1358)—that a drug must be considered "dangerous to health" within the meaning of Sec. 502(j) unless it can be taken in the recommended dosage with *impunity* "by the strong, the *weak*, the old, the *young*, the well, and the *sick*," indiscriminately, *viz.*, in willful or mistaken violation of the directions, instructions and limitations upon its use set forth in the labeling thereof. One of the basic troubles with any such construction of Sec. 502(j) is that it would lead to the absurd result of making virtually all drugs known to *materia medica* "dangerous to health" thereunder, *per se*.

This was forcefully pointed out by the Circuit Court of Appeals for the Sixth Circuit in *Raladam Co. v. Federal Trade Comm.*, 42 F. (2nd) 430, 433 (affirmed by the Supreme Court in 283 U. S. 643), as follows:

> "* * * Much is said in the testimony and the proofs about the toxic or poisonous quality of thyroid extract. There is no reason to doubt that it could be given in such quantity, or in the presence of *such conditions of bodily disease*, that the effect would be very deleterious, whether 'toxic' or not; but it is *equally clear*, and is admitted by the Commission's counsel, that there is *no drug* or *active agent* in the *entire bounds* of *materia medica*, which is not *by the same definition poisonous*." (Italics ours)

Dr. Klumpp, in speaking for the Food and Drug Administration, in charge of administering the statute under consideration, made it clear that it takes the same view of the matter, when he said (C.C.H. Food Drug Cosmetic Law Service, par. 10,216, p. 10,318):

> "But when shall we consider a drug safe? On first impression it might appear that *safety* can be considered *an isolated attribute* of a drug, *but this is not true*, since *every potent drug* carries with it *certain potentialities* for harm." (Italics ours)

In *Coca Cola Co. v. Koke Co.*, 254 U. S. 143, 145, Mr. Justice Holmes, speaking for this Court, put the matter aptly and succinctly, by saying:

> "* * * a drug * * * may be described as a deadly poison or as a valuable item of the pharmacopoeia according to the rhetorical purposes in view."

2. If, on the other hand, Sec. 502(j) is construed to require the recommendation of a dosage which can be taken with safety *according to* the directions, instructions and limitations on its use set forth in the labeling thereof, the requirement is reasonable and capable of fulfillment.

While it is impossible to recommend a dosage of a drug which will be *effective* in the treatment of *certain conditions* and, at the same time, *harmless* in the face of *all other conditions* which contra-indicate its use, no such difficulty is encountered in the requirement of recommending a safe dosage for the treatment of a *particular* condition, accompanied by warnings not to use it in the presence of other conditions which contra-indicate its use.

Such a requirement is *reasonable* and *capable of fulfillment*. It makes the *label* of the drug the *actual* test of

compliance, or *non-compliance*, with the statute. It carries out the purpose of the statute to make *self-medication safer* and *more effective* by requiring *adequate* and *proper labeling*, instead of accomplishing the absurd result of abolishing self-medication to all intents and purposes by making it impossible to label any *useful* drug and in *effective* dosages for such purpose.

Last, but not least, it avoids the vice of destroying a large and valuable industry with a useful function to perform, unless it can be seriously contended that Congress desired to give the medical profession a monopoly over practically all medication, without the usual concomitant safeguard, in such fostered monopolies, of governmental regulation of rates. Regardless of the view some may hold concerning the advisability of giving the medical profession such a monopoly, it will become increasingly apparent in the discussion which follows that such a view is not shared by Congress; and when all is said and done, Congress is the final arbiter in such matters.

In view of the foregoing, the ruling of this Court in *McDermott v. Wisconsin*, 228 U. S. 115, 133, that "the *label* is the *means* of *vindication* and the *basis* of *punishment*" in determining whether a drug is misbranded under a labeling provision—like Sec. 502(j)—is not only *sound*, but particularly *applicable* in the case at bar; and the decision of the Circuit Court of Appeals for the Seventh Circuit holding Marmola *misbranded* under Sec. 502(j)—regardless of the propriety of its labeling—because of the potential dangers *inherent* in self-medication with the Marmola dosage of desiccated thyroid—is clearly in conflict with the decision of this Court in *McDermott v. Wisconsin*, *supra*. Therefore, it is submitted that the foregoing petition for a writ of certiorari is well grounded and should be granted by this Court.

II

In view of the wording of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history, Sec. 502(j) *is not* subject to a construction which will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for *self-medication,* because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription; and this is an important question of federal law which has not been, but should be, settled by this Court.

As has been pointed out in the foregoing petition (*supra*, pp. 6-7, 10-11), the Circuit Court of Appeals for the Seventh Circuit, in affirming the decision of the trial Court herein, placed a construction on Sec. 502(j) *which* will prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for *self-medication,* because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription. In so construing Sec. 502(j), the Circuit Court of Appeals for the Seventh Circuit has decided an important question of federal law which has not been, but should be, settled by this Court; and this is particularly true in view of the fact that unsound character of such a construction of Sec. 502(j) becomes readily apparent upon an examination of the other misbranding provisions of the statute in *pari materia* with Sec. 502(j), and its legislative history—as will be fully hereinafter demonstrated.

A. The scope and proper application of Sec. 502(j) should be determined in the light of the other misbranding provisions of the statute, so that each of them will have some useful function to perform and none of them will be rendered nugatory or inconsistent therewith.

There is probably no principle of statutory construction which is better settled than that the provisions of a statute should be so construed as to be consistent with one another, and so that each of them will have some useful function to perform. The principle under discussion is stated by this Court in *Ex Parte Public National Bank*, 278 U. S. 101, 104, as follows:

> "No rule of statutory construction has been more definitely stated or more often repeated than the cardinal rule that 'significance and effect shall, if possible, be accorded to every word. As early as in Bacon's Abridgment, sect. 2, it was said that "a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant." ' Market Co. v. Hoffman, 101 U. S. 112, 115. * * *"

See also *Hellmich v. Hellman*, 276 U. S. 233, 236-7.

1. If Sec. 502(j) is construed to prevent the labeling of desiccated thyroid for self-medication in *effective* dosages, Sec. 502(e) of the statute will be rendered nugatory—*pro tanto*—because Sec. 503(b) exempts drugs dispensed on a doctor's prescription from Sec. 502(e); with the result that unless desiccated thyroid and the other drugs named therein can be labeled for self-medication in *effective* dosages, Sec. 502(e) has no useful purpose to serve.

A conclusive and unanswerable reason why Sec. 502(j) cannot be construed to prevent the labeling of desiccated thyroid for self-medication in effective dosages is that such a construction would render Sec. 502(e) of the statute nugatory—*pro tanto*—contrary to the principle of statutory construction immediately hereinabove discussed. This is so, because Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from certain of the misbranding provisions of the statute, *including Sec.* 502(e), thereby limiting the application of Sec. 502(e) to the labeling of drugs for self-medication, as follows:

> Sec. 503(b). "A drug dispensed on a written prescription signed by a physician * * * shall * * * be exempt from the requirement of Sec. 502(b) *and* (*e*) * * *." (Italics ours)

Sec. 502(e) of the statute, from which drugs dispensed on a doctor's prescription are exempt as aforesaid, *expressly* applies to the *labeling* of "active," *viz.*, *effective* dosages of *desiccated thyroid*, as follows:

> Sec. 502(e). "A drug shall be deemed to be misbranded—
>
> "If it is a drug that is not designated solely by a name recognized in an official compendium unless its *label* bears (1) the common or usual name of

> the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each *active* ingredient, including the quantity, kind and proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any • • • *thyroid*, or any derivative or preparation of any such substances, contained therein." (Italics ours)

Hence, it follows that unless *effective* dosages of desiccated thyroid can be labeled and used for *self-medication*, the labeling requirements of Sec. 502(e) immediately hereinabove set forth have no purpose to serve so far as desiccated thyroid is concerned, and this provision of the statute is rendered nugatory—*pro tanto*.

Stated differently—the statute by making express provision for the labeling of "active," *viz.*, *effective* dosages of desiccated thyroid for self-medication, has recognized that it may be sold in such dosages for such purpose, provided—*and provided only*—that the *labeling* requirements of the statute are complied with. This being so, it is clear that a construction of the statute which would prevent the labeling of *effective* dosages of drug products containing desiccated thyroid, such as Marmola, for self-medication—not because they are mislabeled, but merely because of the so-called "potential" dangers which may be "inherent" in their use for such purpose—is utterly fallacious.

2. If Sec. 502(j) is construed to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication because of the so-called "potential" dangers "inherent" therein, the requirement of Sec. 502(f) that the labeling of such dosages of such drugs for self-medication shall contain warnings of such dangers becomes mere surplusage.

Sec. 502(f) requires that the labeling of *effective* dosages of a drug for self-medication shall contain

> "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health."

Obviously, this provision has a purpose to serve *only* in the event that, except for the required "warnings," such dosages of a drug might be used for self-medication in the presence of such "pathological conditions or by children." Conversely, if *effective* dosages of drugs are unavailable for self-medication, because of such dangers, no such possibility exists, with the result that the requirement of Sec. 502(f) concerning such "warnings" would be mere surplusage because of the lack of any opportunity for the warnings to be heeded.

To take a homely example, a statutory requirement that a railroad company erect warning signals and other safety devices at grade crossings would be rendered mere surplusage by another provision of the same statute prohibiting the maintenance of grade crossings. By the same token, to construe Sec. 502(j) as preventing self-medication with *effective* dosages of useful drugs—like desiccated thyroid—would render useless the requirements of Sec. 502(f) for the labeling of such dosages of such drugs with warnings of the so-called "potential" dangers "inherent" in self-medication therewith.

3. If, on the other hand, Sec. 502(j) is construed as purely a *labeling* provision designed to make self-medication *safer* by eliminating dangers *created by* improper labeling, Secs. 502(e) and 502(f) will be consistent therewith and have a useful function to perform.

While construing Sec. 502(j) to prevent the labeling and consumption of useful drugs—like desiccated thyroid —for self-medication because of the so-called "potential" dangers "inherent" therein, will render Secs. 502(e) and 502(f) nugatory or mere surplusage as hereinabove pointed out; no such difficulty is encountered if Sec. 502(j) is construed as purely a *labeling* provision designed to require the recommendation of a dosage which is safe for the persons *for whom* the drug is *prescribed* in its labeling.

In other words, when Sec. 502(j) is construed as purely a *labeling* provision the violation of which is to be determined accordingly, it not only will be possible to label desiccated thyroid and other useful drugs for self-medication in compliance with its provisions, but the provisions of Secs. 502(e) and 502(f) become complimentary thereto—instead of being inconsistent therewith—and have a useful function to perform. This being so, such a construction of Sec. 502(j) is the one that must be adopted under the decisions of this Court hereinabove discussed (*supra*, p. 33).

B. Sec. 502(j) should be construed with reference to the principle that an exemption in a statute amounts to an affirmation of its application to all other like matters not exempted, and excludes all other exemptions.

The principle that an exemption in a statute amounts to an affirmation of its application to all other situations not exempted, and excludes all other exemptions, was adopted and applied by this Court at an early day in *Bend v. Hoyt*, 13 Peters 263, 271-2, as follows:

> "* * * the case before us does not turn upon the interpretation of the second clause *standing alone*, but it is materially affected by the fifteenth clause of the same section of the act, which prescribes a rate of duty on manufactures of silk, in the following words: 'On all manufacturers of silk or of which silk shall be a component part, coming from beyond the Cape of Good Hope, ten per centum ad valorem, and on all other manufactures of silk, or of which silk is a component part, five per centum ad valorem, *except sewing silk*, which shall be forty per centum ad valorem.' Now, this language in its positive import, includes all manufactures of silk except sewing silk; and the very exception of sewing silk lends additional force to the conclusion, that no other manufactures of silk were intended to be excepted from the operation of the clause, upon the well known maxim, that *an exception in a statute amounts to an affirmation of the application of its provisions to all other cases not excepted.* * * *" (Italics ours)

See also *Equitable Life Society v. Clements*, 140 U. S. 226, 233; and *Moore Ice Cream Co. v. Rose*, 289 U. S. 373, 377, for more recent decisions of this Court applying the principle under discussion.

1. Sec. 503(b) exempts drugs dispensed on a doctor's prescription from some of the misbranding provisions of the statute *but not from Sec. 502(j)*, with the result that if Sec. 502(j) is construed to prevent the labeling of *effective* dosages of desiccated thyroid for self-medication, it must also be construed to prevent their labeling for use on a doctor's prescription.

As has been seen (*supra*, p. 34), Sec. 503(b) of the statute exempts drugs dispensed on a doctor's prescription from certain of the misbranding provisions of the statute. However, it does not exempt drugs so dispensed from Sec. 502(j). Hence, under the authorities immediately hereinabove discussed, Sec. 502(j) must be construed to apply with equal force to a drug regardless of whether it is labeled for self-medication or for use on a doctor's prescription.

This being so, if *effective* dosages of useful drugs—like desiccated thyroid—cannot be labeled for self-medication without offending Sec. 502(j), they cannot be labeled for use on a doctor's prescription thereunder. Conversely, if such dosages of such drugs can be labeled for use on a doctor's prescription under Sec. 502(j), they can also be labeled for self-medication thereunder.

Therefore, it follows that any effective dosage of any drug, which can be labeled for use on a doctor's prescription, can also be labeled for self-medication; and, as has been seen, the Marmola dosage of desiccated thyroid falls in this category, because it is the "generally established" (R. 115) average dosage of desiccated thyroid prescribed by the medical profession (R. 55, 87, 115, 248, 544, 608, 639, 647, 686, 710-11, 892).

C. If any doubt remains concerning the proper construction of Sec. 502(j), it should be resolved in favor of its purpose and intent as disclosed by its legislative history.

The function to be served and weight to be accorded the legislative history of a statute in arriving at its proper construction is stated in *McCaughn v. Hershey Chocolate Co.*, 283 U.S. 488, 492, as follows:

> "Possible doubts as to the proper construction of the language used should be resolved in the light of its administrative and legislative history. * * *"

See also *Gay v. Ruff*, 292 U.S. 25, 31; and *Fed. Security Admin. v. Quaker Oats Co.*, 318 U.S. 218, 230. In the case last mentioned this Court placed considerable reliance on the legislative history of other provisions of the statute under consideration in this case, in arriving at its decision.

1. The legislative history of the statute discloses that Sec. 502(j) is purely a labeling provision designed to make self-medication safer by requiring adequate and proper labeling, and that it is not designed to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication, merely because of the "potential" dangers "inherent" therein.

Finally, if anything more is needed to demonstrate that Sec. 502(j) is purely a *labeling* provision designed to make self-medication safer by requiring adequate and proper labeling, and that it is not designed to prevent the labeling of *effective* dosages of useful drugs—like desiccated thyroid—for self-medication, merely because of

the "potential" dangers "inherent" therein, it is furnished by the legislative history of the statute. This, fortunately, is available in convenient form for the use of this Court and counsel in the "*Federal Food, Drug and Cosmetic Act*—a Statement of Its Legislative History"—by Charles Wesley Dunn (1st Ed., published 1938).

While there is a tremendous amount of material available in the legislative history, which demonstrates conclusively that Congress had no intention of passing a statute which might be construed to deprive individuals of what Congress regarded as their right of self-medication with effective dosages of useful drugs—like desiccated thyroid—so much of this material is merely cumulative on the point that a few excerpts therefrom should be sufficient to demonstrate the same. The figures in parentheses, appearing in the following discussion, refer to the pertinent pages of Mr. Dunn's Legislative History of the Act.

Before delving into this legislative history in any detailed manner, it is interesting to note that more than six different bills were introduced in Congress during seven different sessions (vii-ix), covering a period exceeding five years, five of which bills were allowed to die before Congress could be induced to pass the present statute. As appears from the legislative history, it did so then only with considerable reluctance, because of the fear that it might possibly be perverted into a ban of self-medication to some extent. In addition, it is worthy of note that the first bill introduced in Congress was drafted in the Department of Agriculture (24) and that Mr. Walter G. Campbell, both then and until very recently Chief of the Food and Drug Administration, a subdivision of the Department of Agriculture, was one of the principal sponsors of the legislation. Consequently, his statements to Congress, regarding the purpose and scope of the legislation are entitled to more than ordinary weight.

The first bill was introduced in the Senate on June 12, 1933, and was known as Senate 1944 (37). Section 4 of that Act provided:

> "Sec. 4. A drug shall be deemed to be adulterated—
>
> "(a) If it *is* or *may be* dangerous to health under the conditions of use prescribed in the labeling thereof." (38-9) (Italics ours)

Hearings were had on Senate 1944 before a subcommittee on December 7 and 8, 1933 (1048). During the course of these hearings, Mr. Campbell made the following pertinent statement:

> "*There is no issue,* as I have told you previously, from the standpoint of the enforcement of the Food and Drugs Act *about self-medication.*
>
> "This bill does not contemplate its prevention *at all.* If it did *a single short section* in the measure could have been drawn up *to that effect.*" (1083) (Italics ours)

It is submitted that the most careful examination of the statute as finally passed fails to reveal any "single short section" which expresses an intention to prevent self-medication to any extent, or even a long one for that matter. Nevertheless, the effect of the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the trial Court's decision herein, is to convert the statute from one that did not contemplate the prevention of self-medication "*at all*" into one that will do away with it *entirely,* if it is followed to its logical conclusion, as it must be, if it is sound—as has been pointed out in the foregoing petition (*supra*, pp. 10-11).

Senate 1944 died in the Senate Committee on Commerce, where it was superseded by a second bill known as Senate 2000 (50). This second bill also died in Committee without any hearings being held on the same, and

was superseded by a third bill known as *Senate* 2800 (67). Hearings were held on this Bill before the Senate Committee on Commerce from February 27 through March 3, 1934 (87). At one of these hearings Mr. Campbell again took occasion to reassure the Senate Committee that the proposed legislation was not designed to interfere to any extent with the right of self-medication, as follows:

> "And let me stop just at this point to comment upon the criticism so extensively voiced by the patent-medicine interest that *the purpose of this bill is to stop self-medication.* This paragraph (a) of section 9* would certainly be unnecessary if it were not contemplated that *self-medication will continue in the future as it has in the past.* Physicians do not need such information; nor would they need but little of the information required by the succeeding paragraphs of this section. All of the provisions dealing with drugs, aside from those recognized in the official compendia, are directed towards safeguarding the consumer *who is attempting to administer to himself.* If this measure passes, self-medication will become infinitely more safe than it has ever been in the past" (1195). (Italics ours)

On the strength of assurances such as these Senator Copeland, Chairman of the Senate Committee, which had held the hearings on Senate 2800, as aforesaid, made a statement "formulated with a view to describing the bill and *its purposes*" (87) and submitted a Committee Report (110) to the Senate regarding the purpose and scope of the proposed bill. In his *statement* Senator Copeland denied emphatically that the bill was intended to prevent self-medication with effective dosages of useful drugs—like desiccated thyroid—as follows:

> "There is no more common or mistaken *criticism* of this bill than *that it denies the right of*

*Section 9 was a *misbranding* section of the bill which Mr. Campbell was then discussing.

> *self-medication,* or, as the objector usually put it, 'You can't take an aspirin tablet without a doctor's prescription.' *Nothing could be further from the truth.* The proposed law simply *contributes to* the safety of self-medication by preventing medicines from being sold as 'cures' unless they really are cures. It requires that drugs which have only palliative effect shall say as much on the label.
>
> * * * * *
>
> "As regards drugs, the bill provides that particularly potent drugs are to be declared. The label must carry a warning against habit-forming drugs and overdosage. We believe these provisions insure *adequate* public protection without imposing unreasonable hardships on anybody" (89-90, 91). (Italics ours)

The pertinent part of the Committee Report which was prefaced by the foregoing *statement* of Senator Copeland, reads as follows:

> "Section 4. Adulterated Drugs.
>
> "Section 4 defines adulterated drugs. Paragraph (a) defines as adulterated a drug which is dangerous to health under conditions of use prescribed in its labeling. There are *no useful drugs* which would be *banned from the market* under this provision since *labeling* with proper directions for use *would remove any worth-while drug* from this ban. * * *" (114-115). (Italics ours)

Another statement in the legislative history of the statute, which discloses that Congress did not intend to put an end to self-medication with effective dosages of useful drugs—like desiccated thyroid—despite its recognition of the so-called "potential" dangers which may be "inherent" therein, but merely intended to make self-medication safer by requiring adequate and proper labeling, appears in a further statement by Senator Copeland

to the Senate concerning the purpose and intent of the bill designated Senate 2800, as follows:

> "There are *many* very *useful* drugs which should be employed only with great care and discretion because in improper dosage or when administered to children or *when the patient is suffering from certain disease complications,* the effect of these drugs may be disastrous. S. 2800 provides *an effective safeguard against these dangers* which cannot be controlled under the present law. It requires that all drugs bear *explicit directions for use* and appropriate *warnings* against their consumption *by children* or *in certain disease conditions* where the use is contraindicated" (162). (Italics ours)

Substantially the same statement appears in the Senate Report (254) and House Report (484) on Senate 5, which is the bill that was finally enacted, as aforesaid.

After *Senate* 2800 had died on the Senate Calendar (188), the Food and Drug Administration made the following statement in its annual report (189) for the fiscal year 1934, by way of explanation of the failure of Congress to pass the proposed legislation:

> "A vast amount of *misinformation* to the effect that the bill if passed would result in destruction of legitimate industries, *interfere* with *the right* of *self-medication,* and deny manufacturers their constitutional rights, was disseminated not only among the industries but among the public." (190) (Italics ours)

On January 4, 1935, *Senate* 5 was introduced by Senator Copeland, and again referred to the Committee on Commerce (191). Hearings on this bill were held before the Committee on March 2, 8 and 9, 1935 (1213); and again Mr. Campbell appeared and reaffirmed his earlier

statements hereinabove discussed concerning the scope and intended purpose of the proposed bill, the pertinent part of which reads as follows:

> "Mr. Chairman. I spoke at length at both of the previous hearings. Most of what I said before, and then, if not everything that I said is applicable in substantial measure to a consideration of the present bill S. 5" (1222).

The Committee submitted its report to the Senate on March 26, 1935 (237), and on the strength of assurances such as Mr. Campbell's again commented on the purpose and scope of the "dangerous drug" provision of Senate 5, which provision is now Sec. 502(j) of the present statute, as follows:

> "Section 401(a) (1) defines a drug as adulterated if it is dangerous to health under the conditions of use prescribed in its labeling or advertising. There are *no useful drugs* which *would be banned* from the market under this provision, *since labeling with proper directions for use* would remove any worth-while drug from this ban. * * *
>
> "It will be noted that this provision in S. 5 differs from a similar provision in at least one of the bills considered by the last Congress, in that *the words 'or may be' have been deleted* before 'dangerous to health.' This is for the reason that there are certain drugs whoes employment is necessary in the treatment of some diseases which, none the less, *may in very exceptional cases prove harmful* to persons to whom they are administered. Their action in such circumstances is comparable to the allergic action of eggs and other common foods, which was discussed in connection with paragraph (a) of section 301. *It is not intended* that this provision *should ban the sale of useful drugs of this kind* when they are *appropriately labeled*" (250) (Italics ours)

At an earlier point in this brief (*supra*, pp. 34-35) it was demonstrated that *if* Sec. 502(j) is construed to prevent self-medication with desiccated thyroid, Sec. 502(e) would be made nugatory. If anything more is needed to demonstrate that the statute was not designed to make effective dosages of *desiccated thyroid* unavailable for self-medication, regardless of its effect on other drugs, it is furnished by the following statement in the Report made to the Senate on the *final* bill, concerning the purpose of Sec. 502(e):

> "Paragraph (e) of this section requires that drugs sold as other than pharmacopoeial or formulary preparations be labeled with their common or usual name, if they have such names, and if they are fabricated from two or more ingredients, the name of each *active* ingredient, including any alcohol. * * * the consumer of drugs certainly has the right to know something of the identity of the active ingredients, *particularly if he is undertaking to medicate himself* and is thus *acting the role of physician to himself.* In such circumstances he has as much right, as does the physician, to know the identity of the drugs he is administering" (253-4). (Italics ours)

Futhermore—and this should be conclusive on the subject—in the Report of the House Committee on the *final* bill, it was again stated:

> "The bill *is not intended to restrict* in any way *the availability of drugs for self-medication.* On the contrary, it is intended to make self-medication safer and more effective" (822). (Italics ours)

To summarize the legislative history of the statute, it discloses, *first*, that the present Act was obtained from Congress only after great travail and in the face of determined opposition because of the persistent fear on the part of many Senators and Congressmen that it might be utilized to deprive individuals of their right of self-

medication; *second,* that the statute would never have been passed except for the repeated assurances of sponsors of the legislation, like Mr. Campbell, to the effect that "There *is no issue* * * * *about self-medication.* This bill does not contemplate its prevention *at all*" (1083); and, *third,* that, even in the presence of such assurances, Congress exercised the greatest caution to revise the language of any provision of the statute which might otherwise be construed to interfere *"in any way"* with the right of self-medication.

In the face of such a legislative history, it is clear that the statute is not open to a construction that will limit the right of self-medication with *properly* labeled drugs—like Marmola—"in *any* way." Congress having taken every possible precaution to preserve such right inviolate, without any limitation *"at all,"* and sponsors of the legislation—like Mr. Campbell—having repeatedly assured Congress that this purpose had been accomplished in the bill as finally passed, the construction of the statute adopted by the lower Courts herein is obviously improper; and this is so no matter how limited an encroachment on the right of self-medication is intended thereby, or how beneficial from a public health standpoint some persons may believe such an encroachment to be. Congress being the final arbiter of such matters, its judgment must be accepted as conclusive; and no appeal therefrom to courts can be had.

In view of the foregoing, it is apparent that Sec. 502(j) is not open to a construction which will prevent the labeling of effective dosages of useful drugs—like desiccated thyroid—for self-medication, because of the potential dangers *inherent* therein, and, at the same time, permit their continued labeling for use on a doctor's prescription.

This is so—among other reasons—because both the wording of the statute and the legislative history reveal that Congress did not "intend to restrict *in any way* the

availability of drugs for self-medication"; but merely desired "to make self-medication safer and more effective" (*supra*, p. 47), by requiring that "active," *viz.*, effective, dosages of desiccated thyroid (*supra*, pp. 34-35, 47) and other useful drugs offered to the public for self-medication be adequately and properly labeled for such purpose (*supra*, pp. 43-46).

The wording of the statute and its legislative history also reveal that Congress had no intention of giving the medical profession a monopoly over dispensing useful drugs—like desiccated thyroid. Sec. 502(e) not only makes specific requirements which apply *solely* to the labeling of *desiccated thyroid*—and the other drugs mentioned therein—*for self-medication* (*supra*, pp. 34-35), but Sec. 502(j) applies with equal force to all drugs regardless of whether they are labeled for self-medication, or use on a doctor's prescription (*supra*, pp. 38-39).

Hence, it is clear that the Circuit Court of Appeals for the Seventh Circuit, in affirming the decision of the trial Court herein, has not only decided an important question of federal law which has not been, but should be, settled by this Court; but it has decided it contrary to well-settled principles of statutory construction and the express intention of Congress as disclosed by the legislative history of the statute. Under these circumstances, it is submitted that the foregoing petition for a writ of certiorari should be granted, in order that this Court may be given the opportunity to review and correct this erroneous decision which is of such vital importance to the public at large.

III

The construction placed on Sec. 502(j) by the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, casts grave doubt upon its constitutionality; and this furnishes an additional reason for granting the foregoing petition for a writ of certiorari.

An additional reason for granting the foregoing petition for a writ of certiorari is that the decision of the Circuit Court of Appeals for the Seventh Circuit, affirming the decision of the trial Court herein, places a construction on Sec. 502(j) which casts grave doubt on its constitutionality as being (1) an improper interference by Congress in a matter of purely local concern; (2) an unwarranted attempt to prohibit the right of individual citizens of this country to medicate themselves with effective dosages of useful drugs—like desiccated thyroid—without any showing of harm to the public, in general, as a result of their so doing; and (3) a provision the violation of which entails severe penalties and forfeitures without furnishing any fair or ascertainable standard for gauging compliance therewith in advance of prosecution and punishment—all as more fully hereinafter pointed out.

A. If two constructions of Sec. 502(j) are possible, the one should be selected which will avoid doubt as to its constitutionality.

Few principles of statutory construction are better established or more frequently applied than that a statute should be construed, if possible, in such a manner as to avoid doubt concerning its constitutionality. The principle referred to is well stated in *United States v. Standard Brewery*, 251 U. S. 210, 220, as follows:

"Furthermore, we must remember in considering an act of Congress that a construction which *might* render it unconstitutional *is to be avoided.* * * * " (Italics ours)

For more recent decisions of this Court to the same effects, see *United States v. Shreveport Grain & Elevator Co.*, 287 U. S. 77, 81-2; and *N. W. Bell Telephone Co. v. Railway Comm.*, 297 U. S. 471, 480.

1. If Sec. 502(j) is construed as being designed to put an end to self-medication with effective dosages of useful drugs—like desiccated thyroid—within the various States, doubt will be cast upon its validity because it is questionable whether Congress has the power to legislate concerning such matters.

In *Linder v. United States*, 268 U. S. 5, 18, this Court, in reversing the conviction of a physician for an alleged violation of the Narcotic Act, made the following pertinent remarks:

"Obviously, direct control of medical practice in the States is beyond the power of the Federal Government. Incidental regulation of such practice by Congress through a taxing act *cannot extend to matters plainly inappropriate and unnecessary* to reasonable enforcement of a revenue measure. * * *" (Italics ours)

A later decision of this Court to the same effect is that of *Nigro v. United States*, 276 U. S. 332, 341, wherein it was held:

"In interpreting the Act, we must assume that it is a taxing measure, for otherwise it would be no law at all. If it is a mere act for the purpose of *regulating* and *restraining the purchase* of the

> opiate and other drugs, it is beyond the power of Congress and must be regarded as invalid. * * *" (Italics ours)

If any attempt to restrain the purchase and use of narcotics within the various States is deemed to be beyond the powers of Congress as this Court held in the decisions immediately hereinabove discussed, it is submitted that a similar attempt to put an end to self-medication with useful and relatively harmless drugs—like desiccated thyroid—within the various States would be so for the same reason. In any event—and this is all that is necessary for the purposes of arriving at a decision herein—there can be little question but that construing Sec. 502(j) in such a manner will cast doubt upon its constitutionality, with the result that it is a construction which should be avoided.

2. If Sec. 502(j) is construed as an attempt by Congress to deprive individuals of their right of self-medication with effective dosages of useful drugs—like desiccated thyroid—its validity will be open to serious question.

Even more serious doubts concerning the constitutionality of Sec. 502(j) will be raised by a construction thereof which deprives individuals of what has always been considered their inalienable right to self-medicate with useful drugs—like desiccated thyroid—in the absence of any public necessity for depriving them of such right. It is fundamental, under our Constitution, that private rights shall not be called upon to yield merely because a majority feel that the individual seeking their exercise should be deprived of the privilege *for his own good*. The right of the individual to regulate his private life and solve his private health problems as he sees fit—even though unwisely in the view of persons who consider

themselves more enlightened—so long as he does not encroach upon the rights of others, has always been considered one of our fundamental liberties guaranteed by the Constitution. Indeed, the thought has often been expressed that without such a guarantee the Constitution would never have been ratified or adopted.

It may be that the layman who doctors himself with any drug has a fool for a patient. Likewise, it may be that a person who attempts to cure his illness by resorting to Christian Science, chiropractics, osteopathy, homeopathy, physical culture, mineral baths, taking the sun cure, etc., is foolish and unenlightened. The man who eschews all drugs and all medical supervision in his search for health may be more or less wise than the one who makes a choice between self-medication with certain drugs and a "competent" physician. Nevertheless, who can gainsay that our Constitution has guaranteed to each of us the inalienable right to follow our own dictates in such matters—even in the face of our neighbors' disapprobation—provided only that we do not jeopardize our neighbors' health in so doing.

In the recent case of *W. Va. Bd. of Education v. Barnette*, 319 U. S. 624, 630, 638, 639-40, this Court reversed itself in order to safeguard individual liberties—far less valued, universally—against unnecessary encroachment by governmental authority. The pertinent parts of this Court's opinion, holding unconstitutional a requirement that teachers and school children salute the flag, read as follows:

> "The freedom asserted by these appellees *does not bring them into collision with rights asserted by any other individual.* It is such conflicts which most frequently require intervention of the State to determine where the rights of one end and those of another begin. But the refusal of these persons to participate in the ceremony *does not interfere with or deny rights of others to do so.* • • •
>
> • • • • •

"The very purpose of a Bill of Rights was to withdraw certain subjects from the vicissitudes of political controversy, *to place them beyond the reach of majorities and officials and to establish them as legal principles* to be applied by the courts. One's right to life, liberty, and property, to free speech, a free press, freedom of worship and assembly, and other fundamental rights *may not be submitted to vote; they depend on the outcome of no elections.*

"* * * They are susceptible of restriction *only* to prevent grave and *immediate danger* to interests which the state may lawfully protect. * * *

"Nor does our duty to apply the Bill of Rights to assertions of official authority depend upon our possession of marked competence in the field where the invasion of rights occurs. * * * We cannot, because of modest estimates of our competence in such specialties as public education, withhold the judgment that history authenticates as the function of this Court when liberty is infringed." (Italics ours)

See also *Jacobson v. Massachusetts,* 197 U.S. 11, wherein the constitutionality of a statute providing for the compulsory vaccination for smallpox was sustained *solely* because of the greater public necessity involved; and *Meyer v. Nebraska,* 262 U.S. 390, wherein a statute prohibiting the teaching of foreign languages to grade school pupils was invalidated because of the lack of such public necessity.

Looking at the situation under consideration in the instant case, it is perfectly clear that there is no public necessity for preventing an individual from medicating himself with useful drugs—like desiccated thyroid—if, as, and when he sees fit. Conversely, there is no public necessity for requiring the layman to pay unwilling tribute to the medical profession to obtain these drugs. His

failure to try to find a "competent" physician every time he wants to take some medicine "does not interfere with or deny rights of others to do so," nor does it cause "grave and immediate danger" to *others,* as this Court so aptly states the test of "public necessity" in the *Barnette* case, *supra.*

Therefore, it is submitted that, under the foregoing decisions of this Court, the right of self-medication with effective dosages of useful drugs—like desiccated thyroid —is one preserved by the Constitution; and any statute which attempts to infringe the same is of doubtful validity, to say the least. This being so, the construction of Sec. 502(j) which deprives the public of this right is one which must be avoided.

3. Unless Sec. 502(j) is construed as purely a labeling provision the violation of which is to be determined accordingly, doubt will be cast upon its constitutionality, because of its failure to furnish a reasonable standard of compliance therewith which is ascertainable in advance of prosecution.

Finally, a statute to be constitutional must provide a fair standard or reasonable test that will enable persons subject to its provisions to determine in advance of prosecution what they must do in order to comply therewith, instead of waiting to find out in criminal or forfeiture proceedings brought for the alleged violation thereof.

In *United States v. Cohen Grocery Co.,* 255 U.S. 81, 89, this Court, in holding the Lever Act unconstitutional, made the following pertinent remarks:

> "* * * It confines the subject-matter of the investigation which it authorizes to *no* element *essentially inhering in the transaction as to which it provides.* It leaves open, therefore, *the widest con-*

> *ceivable inquiry, the scope of which no one can foresee and the result of which no one can foreshadow or adequately guard against.* In fact, we see no reason to doubt the soundness of the observation of the court below, in its opinion, to the effect that, to attempt to enforce the section would be the exact equivalent of an effort to carry out a statute which in terms merely penalized and punished *all acts detrimental to the public interest when unjust and unreasonable* in the *estimation* of the court and jury." (Italics ours)

To the same effect see *Connally v. General Construction Co.*, 269 U.S. 385, 391-5, wherein this Court's decisions on the question are gathered together and rationalized.

Applying the ruling in the foregoing decisions to the instant case, no standard is or could be provided in the statute which would enable a manufacturer or distributor of a drug to anticipate and prevent a person from taking it *in disregard* of the directions, instructions and limitations upon its use in the labeling thereof. It is common knowledge that even drugs dispensed on a doctor's prescription are not infrequently taken *in violation of* his instructions or by persons *other than those* for whom he has prescribed them. Clearly, it can not be contended that any such test should be applied to effective dosages of useful drugs dispensed on a doctor's prescription; and, yet, as has been shown (*supra*, p. 39) Sec. 502(j) applies with equal force to all drugs whether they are to be used for self-medication or on a doctor's prescription.

The statute contains no list of "dangerous" drugs, nor any formula which will enable anyone to segregate them from the other drugs in *materia medica*, except that the lower Courts' definition of when a drug is "dangerous to health" within the meaning of Sec. 502(j) includes virtually all drugs known to *materia medica*—as has been pointed out in the foregoing petition (*supra*, pp. 6-7, 10-11).

Furthermore, under the construction placed on Sec. 502(j) by the lower Courts herein, the dangerous character of a drug in a given case would apparently depend on a highly variable factor entirely beyond the control of the manufacturer or distributor of the drug, namely, whether some prospective consumer might, in the future, disregard the directions, instructions, and warnings in the labeling, and get into difficulty as a result of so doing. Thus, the violation of the statute would depend on "no element essentially inhering in the transaction as to which it provides," and this was regarded as a fatal defect by this Court in *United States v. Cohen Grocery Co., supra.*

4. If, on the other hand, Sec. 502(j) is construed as purely a labeling provision the violation of which is to be determined accordingly, such a construction is not only sensible and consistent with its language but will avoid any doubt as to its constitutionality.

In *McDermott v. Wisconsin*, 228 U.S. 115, 131, hereinabove discussed in another connection (*supra*, pp. 24-28, 31) this Court made the following pertinent statement as to why *misbranding* provisions—like Sec. 502(j)—should be construed as purely *labeling* provisions the violation of which should be determined accordingly:

> "The *object* of the statute, is to prevent *the misuse of the facilities of interstate commerce in conveying to* and *placing before* the consumer misbranded and adulterated articles of medicine or food, * * * This is *the only practical or sensible construction of the act*, and, for the reasons we have stated, we think the requirements of the act *as so construed* clearly *within the powers* of Congress over the facilities of interstate commerce, and such has been the construction generally placed upon the act by the Federal courts." (Italics ours)

Thus, if Sec. 502(j) is construed as purely a *labeling* provision the violation of which is to be determined accordingly—as its wording and legislative history show it should be—such a construction is not only *sensible* and *consistent with its language*, but all of *the doubts regarding its constitutionality*, which would arise under the construction placed thereon by the lower Courts herein, are immediately dispelled. Sec. 502(j) then becomes a regulation of the *labeling* of drugs *for* shipment in interstate commerce, with the result that the *label* which the manufacturer or distributor of a drug places thereon furnishes the *sole* criterion of whether it is *misbranded* thereunder. Hence, a reasonable standard of compliance therewith, "inhering in the transaction" to which the manufacturer or distributor of the drug is a party, is thereby provided.

Furthermore, under such a construction, the validity of Sec. 502(j) is not open to question as being an unwarranted attempt to interfere in purely local affairs, or to deprive individuals of their inalienable right to medicate themselves. This being so, it is clear that this is the construction of Sec. 502(j) that should be adopted.

Therefore, it is submitted that doubtful constitutionality of Sec. 502(j), when it is construed as the lower Courts herein have construed it, furnishes an additional reason for granting the foregoing petition for a writ of certiorari. This is particularly true in view of the ruling of this Court in *McDermott v. Wisconsin, supra*, to the effect that, when a *misbranding* provision—like Sec. 502(j) —is construed as purely a *labeling* provision the violation of which is to be determined accordingly, it is "clearly *within the powers* of Congress over the facilities of interstate commerce"—with the result that: "This is the *only practical* or *sensible* construction" such a *misbranding* provision.

IV

The record herein does not contain evidence which —as a matter of law—will support a finding that Marmola is *misbranded* under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly; and this furnishes still another reason for granting the foregoing petition for a writ of certiorari.

Finally, the foregoing petition for a writ of certiorari should be granted because the record in this case does not contain evidence which—as a matter of law—will support a finding that Marmola is *misbranded* under Sec. 502(j), when it is construed as purely a *labeling* provision the violation of which is to be determined accordingly; and this is not only the *proper* but the "*only practical* or *sensible* construction" of a misbranding provision—like Sec. 502(j)—has been decided by this Court in *McDermott v. Wisconsin*, 228 U.S. 115, 130, 131, 132-3 (*supra*, pp. 24, 57). Moreover, this is the required construction (1) in view of the wording of Sec. 502(j), the wording of the other misbranding provisions of the statute in *pari materia* therewith, and its legislative history (*supra*, pp. 25-31, 32-49), and (2) to avoid casting grave doubt upon its constitutionality (*supra*, pp. 50-58).

As has been pointed out (*supra*, pp. 5-10), this case was tried by the Government and decided on the theory that it is only necessary to show that there are certain potential dangers *inherent* in the use of a drug for *self-medication*, in order to prove that it is misbranded under Sec. 502(j). This being the Government's theory it devoted its time to introducing proof of this character; and such proof is immaterial on the question of whether Marmola is *misbranded* under a *labeling* provision—like Sec. 502(j).

Furthermore, the material proof in the record—relying on the testimony of the Government's witnesses alone—discloses that Marmola is labeled according to approved medical standards, as has been pointed out *(supra,* pp. 3-5). Under these circumstances, the evidence to support a finding that Marmola is misbranded under Sec. 502(j) is not only completely lacking, but, if any finding is to be made, it must be that Marmola is properly labeled thereunder.

In other words, this is not merely a case where there is a complete failure of proof to support a finding, but the proof is such as to require a contrary finding—as a matter of law. Therefore, it is submitted that the foregoing petition for a writ of certiorari should be granted for this and the other reasons set forth in the foregoing pages of this brief.

CONCLUSION

It is therefore respectfully submitted that this case is one calling for the exercise by this Court of its supervisory powers, by granting a writ of certiorari and thereafter reviewing and reversing the decision of the Circuit Court of Appeals for the Seventh Circuit, which affirmed the decision of the trial Court herein.

Respectfully submitted,

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